

K053644

FEB 9 2006

510(K) SUMMARY

Common/Usual Name:	Topical Hemostat
Product Trade Name:	ThrombiGel thrombin/gelatin foam hemostat
Classification Name:	Unclassified, product code FRO
Manufacturer:	Vascular Solutions, Inc. 6464 Sycamore Court Minneapolis, Minnesota 55369
Establishment Registration:	2134812
Contact:	Linda Busklein Sr. Regulatory Affairs Associate (763) 656-4217 phone, (763) 656-4250 fax
Performance Standards:	No performance standards have been developed under section 514 for this device.
Device Description:	The ThrombiGel thrombin/gelatin foam hemostat consists of a lyophilized gelatin foam pad containing thrombin, sodium carboxymethylcellulose, and calcium chloride. The ThrombiGel is applied directly over the source of bleeding, creating a physical barrier to blood flow through the application of adjunctive manual compression. The lyophilized components (thrombin, CMC, and calcium chloride) establish an environment in which a natural blood clot can build and form a physical barrier to bleeding. The thrombin facilitates hemostasis by enhancing the surface activated clotting cascade through enzymatic cleavage and conversion of fibrinogen to fibrin.
Intended Use:	The ThrombiGel is applied topically and is indicated as a trauma dressing for temporary control of moderate to severely bleeding wounds and for the control of surface bleeding from vascular access sites and percutaneous catheters or tubes.
Summary of Non-Clinical Testing:	Testing included assessment of the physical properties of the lyophilized pad and its ability to achieve its intended use. The results of the tests confirmed the suitability of the device for its intended use.
Predicate Devices:	ThrombiGel thrombin/gelatin foam hemostat (K050511)
Conclusions:	The ThrombiGel foam hemostat pad is substantially equivalent to the currently marketed ThrombiGel foam hemostat based on a comparison of the indications for use and the technological characteristics of the device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 9 2006

Ms. Linda Busklein
Senior Associate, Regulatory Affairs
Vascular Solutions, Inc.
6464 Sycamore Court
Minneapolis, Minnesota 55369

Re: K053644

Trade/Device Name: ThrombiGel™ thrombin/gelatin foam hemostat
Regulatory Class: Unclassified
Product Code: FRO
Dated: December 28, 2005
Received: December 30, 2005

Dear Ms. Busklein:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

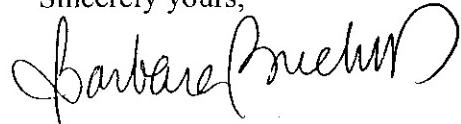
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally

Page 2 – Ms. Busklein

marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number:

K053644

Device Name: **ThrombiGel™ thrombin/gelatin foam hemostat**

Indications for Use:

The ThrombiGel thrombin/gelatin foam hemostat is applied topically and is indicated as a trauma dressing for temporary control of moderate to severely bleeding wounds and for the control of surface bleeding from vascular access sites and percutaneous catheters or tubes.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Carlaire BruchW
(Division Sign-Off)
Division of General and Neurological Devices

Page 1 of 1

510(k) Number K053644